

**Rejection of Claims 15-20 Under 35 U.S.C. § 112, Second Paragraph**

Claims 15-20 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. According to the Examiner, the claims fail to recite the amount of active compound present in the composition. Claims 15-20 have been amended to recite that an effective amount of the compound is present in the composition. One of skill in the art, from reading the specification as filed, would be aware of what is meant by “effective amount.” For example, see page 3, lines 25-27, of the specification as filed, wherein it recites that a sufficient dosage preferably would provide a blood concentration of from 5 to 10,000 nM. Thus, it is believed that claims 15-20, as amended, are definite and fully supported by the specification as filed.

The Examiner also indicated that there is no antecedent support in claim 20 for “5-androstene-3 $\beta$ ,17 $\alpha$ - diol.” Claim 19 has been amended to provided proper antecedent support for this compound.

In light of the above, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

**Rejection of Claims 15-18 Under 35 U.S.C. § 103(a)**

Claims 15-18 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Tindall et al (U.S. Patent No. 2,845,381) taken with Peat (U.S. Patent No. 4,628,052). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The present invention is drawn to compositions comprising 5-androstene-3 $\beta$ ,17 $\alpha$ -diol or an ester or ether thereof. The present invention is also drawn to compositions wherein the 5-androstene-3 $\beta$ ,17 $\alpha$ -diol or an ester or ether thereof is part of a cyclodextrin inclusion complex.

Tindall et al disclose the use of androstane and androstene derivatives for cosmetic uses. The Examiner points to column 2, line 43, of Tindall et al as disclosing an active compound of the present invention. However, at column 2, line 43, what is disclosed is Androstanediol-3 $\beta$ :17 $\alpha$ . In contrast, the present invention uses 5-androstene-3 $\beta$ ,17 $\alpha$ -diol or an ester or ether thereof. The difference between an “androstane” and an “androstene” compound is the presence of a double bond in androstene which is not present in androstane. This is a huge difference and significantly changes the properties of the compounds. Thus, Tindall et al does not disclose or even suggest the active compounds of the present invention, and thus could not possibly disclose or suggest compositions comprising such compounds.

Peat does not solve the deficiencies of Tindall et al. Peat discloses using dehydroepiandrosterone and other anesthetic steroids for treating arthritis and other joint disabilities. Peat does not disclose or even suggest a composition comprising 5-androstene-3 $\beta$ ,17 $\alpha$ -diol or an ester or ether thereof, and thus even if combined with the disclosure of Tindall et al, would not disclose or suggest the claims of the present invention.

In light of these remarks, applicant respectfully requests withdrawal of this rejection under 35 U.S.C. § 103(a).

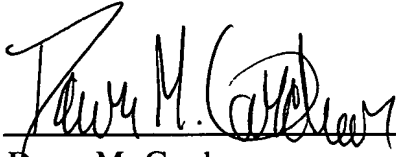
CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned so that prosecution of the subject application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:   
Dawn M. Gardner  
Registration No. 44,118

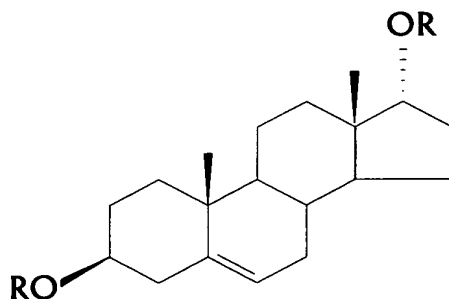
P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: June 12, 2001

**Attachment to Amendment and Reply dated June 12, 2001**

**Marked-up Claims 15 and 19**

15. (Twice Amended) A composition of matter comprising an effective amount of 5-androstene-3 $\beta$ ,17 $\alpha$ - diol or an ester or ether thereof of the formula:

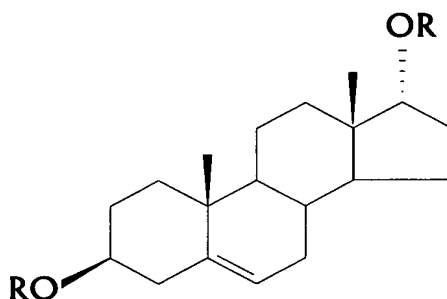


wherein R may be H, alkenyl of 2-8 carbons, alkyl of 1-8 carbons, phenylalkyl of 1-4 carbons, phenyl or COR<sub>2</sub>, wherein R<sub>2</sub> may be H, alkyl of 1-8 carbons, alkenyl of 2-8 carbons, phenylalkyl wherein the alkyl has 1-4 carbons (including benzyl) or R<sub>2</sub> may be phenyl, and wherein any phenyl moiety may have up to three substituents chosen from among hydroxy, carboxy of 1-4 carbons, halo, alkoxy of 1-4 carbons, alkyl of 1-4 carbons, or alkenyl of 2-4 carbons and wherein any alkyl may be a straight chain, branched chain, or the alkyl may be wholly or partially cyclized, in a pharmaceutically acceptable carrier, said formulation being in the form of a capsule or tablet.

**Attachment to Amendment and Reply dated June 12, 2001**

**Marked-up Claims 15 and 19**

19. (Twice Amended) A composition of matter comprising an effective amount of 5-androstene-3 $\beta$ ,17 $\alpha$ - diol or an ester or ether of the formula:



Wherein R may be H, alkenyl of 2-8 carbons, alkyl of 1-8 carbons, phenylalkyl of 1-4 carbons, phenyl or COR<sub>2</sub>, wherein R<sub>2</sub> may be H, alkyl of 1-8 carbons, alkenyl of 2-8 carbons, phenylalkyl wherein the alkyl has 1-4 carbons (including benzyl) or R<sub>2</sub> may be phenyl, and wherein any phenyl moiety may have up to three substituents chosen from among hydroxy, carboxy of 1-4 carbons, halo, alkoxy of 1-4 carbons, alkyl of 1-4 carbons, or alkenyl of 2-4 carbons and wherein any alkyl may be a straight chain, branched chain, or the alkyl may be wholly or partially cyclized, in a pharmaceutically acceptable carrier, wherein said 5-androstene-3 $\beta$ ,17 $\alpha$ - diol or ester or ether thereof is part of a cyclodextrin inclusion complex.